As of January 14, 2002

Read-ahead for Assistant Secretary of Defense for Health Affairs on Anthrax Vaccine Immunization Program

From: John A. Richardson, Col, USAFR, ret.; Tel. 919-444-1042

Date and Time: January 14, 2002 at 1400-1445

Location: Pentagon Room 3E1082

Lead Briefer: Col (ret.) John Richardson, USAFR

Attendees: Col (ret.) Sammie Young, LtCol John Michels; Maj Russ Dingle; Maj Tom Rempfer

Issue: AVIP Implementation and Future Prospects for Force Health Protection (FHP)

1. Background: Recommendation to resume mandatory force-wide anthrax vaccinations will be made by ASD(HA). Resolution of on-going legal and safety issues could limit continued controversy and adverse retention impact of AVIP. Investigation and correction of, systemic failures of military medical bureaucracy may provide a transformational approach to future DoD medical readiness doctrine and more objective analysis of FHP alternatives.

2. Key Points:

   - Policy – One-sided analysis driven by politics and bureaucratic imperatives, not medicine or concern for troops. Knee-jerk to Khobar Towers bombing and failure to confront Iraq.

   - Science/Medicine – Subordinate to political, bureaucratic and operational priorities.

   - Law – Initial lawful implementation consciously abandoned in Mar 1997; AVIP later ignored new law in 1998 specifically intended to protect servicemembers' health rights.

   - Ethics – Compromised because military medicine is held to a lower standard of accountability than operational branches of the military, or civilian medicine.

3. Recommendations: ASD(HA):

   - Adopt biological defense strategy outlined in USD(P&R) memo to SecDef, 10 Aug 2001.

   - Use BioPort vaccine only under provisions of Title 10 USC 1107 and DODD 6200.2.

   - Establish multi-disciplinary "Red Team" to provide balanced oversight of FHP programs.

AVIP Implementation
and
Future Prospects for
Force Health Protection

Background Read-Ahead
For ASD(HA) Meeting
January 14, 2002

Secretary of Defense Cohen on anthrax vaccine, Al Jaber Airbase, Kuwait March 9, 1999:

USAF airman: "What about anthrax?"

Mr. Cohen: "If you were not properly protected against that, I would be derelict in my duties sending you out in an environment in which you weren't properly protected."

Secretary of Defense Rumsfeld on anthrax vaccine, DoD press briefing, October 25, 2001:

Reporter: "Are you taking the anthrax vaccine, Mr. Secretary?"

Mr. Rumsfeld: "No."

Reporter: "You're not being inoculated, you're not taking a series of tests."

Mr. Rumsfeld: "No. No."

Reporter: "All right. No vaccine."

Mr. Rumsfeld: "No, no, no."

Bios of Meeting Attendees

Russell E. Dingle (Major, USAFR) -- A 1979 graduate of the University of Maine, he was commissioned in the Air Force through Officers Training School. He is a former A-10 fighter pilot and instructor pilot with 18 years service on active duty and in the Air National Guard, in the U.S and in Europe. Major Dingle was a flight commander for118th Fighter Squadron, Connecticut Air National Guard, until he was forced to leave the unit over the anthrax vaccine policy. Assigned as a member of CTANG AVIP research "tiger team" and tasked by the former wing commander to investigate the anthrax vaccination policy before it was implemented at that unit. Testified at first congressional hearing on AVIP on 24 March 1999. Working with Congress, GAO, and Connecticut Attorney General's office on AVIP debacle. Currently Connecticut Admission Liaison Officer for USAF Academy. He is a captain for American Airlines in his civilian career.

John J. Michels, Jr. (LtCol, USAFR, Judge Advocate General) -- A1977 graduate of the US Air Force Academy. He served in operational positions as an electronic warfare officer on RC-135 aircraft before attending Duke Law School. He served as an active duty JAG for six years, and finished his active duty service as an instructor at the USAF Judge Advocate General School, where he continues to serve as a reservist. He is currently a member of the Board of Governors of the Virginia State Bar's Military Law Section. In private practice, Mr. Michels is a partner of McGuire Woods, LLP, in McLean, Virginia, and is a litigation attorney with an extensive labor and employment law practice. Mr. Michels co-authored the legal brief prepared to defend former USAF Major Sonnie Bates for refusing the anthrax vaccine. He is also a pro-bono attorney in the Declaratory Judgment lawsuit filed by former Major Sonnie Bates, USAF, and Captain John Buck, USAF, seeking a ruling from a federal court on the legal status of the anthrax vaccine. He has also testified before the House Government Reform Committee on the informed consent aspects of the AVIP policy.

Thomas L. Rempfer (Major, USAFR) -- A 1987 distinguished graduate of the USAF Academy. Currently an Individual Mobilization Augmentee in the US Air Force Reserve having served as a fighter pilot in the F-16, F-117, and the A-10 in the U.S., South Korea, and Southwest Asia. A life member of the National Guard Association, the VFW and the USAF Academy Association of Graduates. A member of Connecticut National Guard AVIP research team tasked to investigate the anthrax vaccination policy before it was implemented at his former Guard unit. Testified at first congressional hearing on the DoD anthrax vaccine policy on 24 March 1999. He has assisted Congress and the Connecticut Attorney General's office research the policy and legal issues related to AVIP. Also serves as an Admission Liaison Officer for the USAF Academy. He is a pilot for American Airlines in his civilian career.

John A. Richardson (Col, USAFR) -- Commissioned in 1977 through ROTC following graduation from the University of North Carolina. He flew T-38's and F-16's in the Air Force from 1978-1985, in the U.S. and South Korea. He then transferred to the SC Air National Guard and flew F-16's there from 1985-1992, including 43 combat missions in the Gulf War. Transferred to the Air Force Reserve in 1992 and served as a policy analyst on the Joint Staff, J-5, Directorate for Strategic Plans and Policy. From 1998-1999 he attended a one-year military fellowship at Harvard University's John F. Kennedy School of Government. He was assigned in 1999 to the Headquarters USAF Strategic Plans (XPX) directorate to work Reserve/Guard integration issues, and retired in May 2001. A captain with American Airlines in his civilian career.

Sammie R. Young (Col, USAFR, ret., Medical Service Corps) -- Served a 41-year tenure in government, first in the Air Force and then nearly 30 years as an investigator and regulatory official with the Food and Drug Administration (FDA). From 1974-1983 he was Compliance Director of the FDA organization that regulated vaccines (and all biologics). He has provided expert advice to Congress, the General Accounting Office, and lawyers litigating the anthrax vaccine's regulatory and legal status with respect to the Food, Drug and Cosmetic Act and the Public Health Service Act. As a military reserve officer he was executive officer of a mobile hospital squadron and later managed blood programs for DoD at the Pentagon. Colonel Young is now retired.

TAB A
Policy

Issue: The decision to pursue the anthrax vaccine as the prototype of a Force Health Protection program was made by a small group of Pentagon civilian appointees who bypassed the normal military staff review. They acted at the urging of a Clinton White House obsessed with the political consequences of military casualties after the Mogadishu and Khobar Towers incidents.

AVIP Point: "This is a force protection issue. This is essentially the first step in a medical force protection program under a health force protection program that the President has talked about, I believe, on 8 November. This will be the prototype program where we will roll that out."

-- Senior military medical officer unwilling to be named, DoD press briefing announcing AVIP, 15 Dec 1997 (possibly Rear Admiral (Dr.) Mike Cowan, M.D., Joint Staff, J-4)

AVIP Point: "The military and civilian leadership of the government is being held to the extremely high standard of avoiding adverse health effects subsequent to military service—service that by definition, tradition, and reality is inherently hazardous."

--Presidential Review Directive 5, National Security Council, August 1998 (implementing policy document responding to statement by President Clinton announcing recommendations of the Special Report of Presidential Advisory Committee on Gulf War Veterans' Illnesses, White House Press office, 8 Nov 1997)

Counterpoint: "Military leaders initially were dubious about the need for the anthrax vaccine...But some senior civilian Defense Department officials, who ardently support the vaccination plan, ultimately convinced the military leaders during months of internal review...senior defense officials eager to institute a broad vaccination program departed from normal departmental practice this spring and organized two meetings that included vice chiefs of the Army, Navy, Air Force and Marine Corps and civilian experts. "The meetings were unusual in that we were starting at the top instead of trying to staff an issue from the bottom up," said one of the organizers.

--"Military Chiefs Back Anthrax Inoculations", Washington Post, 2 Oct 1996

Counterpoint: "Fixating on the danger of fending off a biological calamity - a danger that has existed virtually unnoticed for decades - enables policymakers to avert their eyes from the larger disconcerting truth that there is no end in sight to the exertions that Americans will be obliged to make in pursuit of President Clinton's interpretation of the Wilsonian vision..."

-- Boston University Professor Andrew J. Bacevich, PhD, (Colonel, US Army, ret.), "Bad Medicine for Biological Terror" (Orbis/Foreign Policy Research Institute, Spring 2000)

TAB A
Policy

Issue: In responding to the concerns of senior DoD policymakers, proponents of a mandatory anthrax vaccine immunization program ignored earlier objective DoD acknowledgements of its high reactogenicity and questionable efficacy.

AVIP Point: "It has recently been brought to my attention that you have raised some concern over the safety of the vaccine. Based on your concern, I directed my Special Assistant for Biological/Chemical Matters, BG Russ Zajtchuk, to conduct a re-evaluation of the supporting technical data. His findings uphold the safety and effectiveness of this vaccine."

-- ASD(HA) Dr. Stephen Joseph, M.D., memo to Vice Chairman of the Joint Chiefs of Staff, 25 July 1995

Counterpoint: "There is no vaccine in current use which will safely and effectively protect military personnel against exposure to this hazardous bacterial agent. A licensed vaccine against anthrax, which appears to afford some protection from the disease, is currently available for human use...The vaccine is, however, highly reactogenic, requires multiple boosters to maintain immunity and may not be protective against all strains of the anthrax bacillus."

-- 1985 U.S. Army Request for Proposal for a replacement for the anthrax vaccine

Counterpoint: "Current vaccines, particularly the anthrax vaccine, do not readily lend themselves to use in mass troop immunization for a variety of reasons: the requirement in many cases for multiple immunizations to accomplish protective immunity, a higher than desirable rate of reactogenicity, and, in some cases, lack of strong enough efficacy against infection by the aerosol route of exposure."

-- 1989 letter from then-Assistant Secretary of Defense Robert B. Barker to Senator John Glenn, then- Chairman of the Senate Governmental Affairs Committee

Counterpoint: "... unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the AVA. These concerns stem from: a) the limited use of the vaccine to date, i.e., tests prior to approval of the vaccine by the Food and Drug Administration are on too small a scale to permit accurate assessment of types and severity of adverse reactions (only widespread use can provide this assessment); and b) insufficient experience in mass immunization programs to truly evaluate the efficacy of the vaccine. Moreover, there is no way to predict whether the pathogen against which the vaccine may be used will be sufficiently similar to the pathogen used in tests to ensure vaccine efficacy."

-- 1992 Secretary of the Army Togo West, letter indemnifying the anthrax vaccine manufacturer

TAB A
Policy

Issue: The Army, as executive agent over biological warfare defense programs, led a one-sided AVIP development and implementation that precluded an objective "second opinion" from other Services, the Joint Staff or OSD. This dynamic appears driven by non-clinician Army medical corps officers whose priorities were other than health care and whose values are out of step with the society they serve.

AVIP Point: "Today, during his commencement address at the U.S. Naval Academy, President Clinton emphasized the importance of this initiative.... The Secretary of the Army will be the Executive Agent for the Department's Anthrax Vaccination Program. The Army, on behalf of the Executive Agent, will manage and administer the overall program and monitor the Services' progress of their respective implementation plans."

> -- DoD press release, 22 May 1998, coincident with President Clinton announcing Presidential Decision Directive 68, a counter-terrorism initiative of which AVIP was a centerpiece of the Clinton Administration's "doing something" about terrorism.

AVIP Point: "This is a warfighter position...how they want to handle soldiers who refuse medical care. We certainly don't want a squad where some soldiers are immunized, others aren't cause they refuse...it's a good immunization...if we believe in it, then we give it. Remember, it's not just anthrax we're talking about, it's the whole pallet of immunizations. We CANNOT open the gates...allow soldiers who refuse to administratively get out...this is a HUGE problem in the Army right now...without anthrax adding to it. GAO reports we're discharging over 30% of our first term soldiers as is...it's a big readiness issue. If we allow soldiers to refuse anthrax, why not any other of the immunizations?"

> -- Col Fred Gerber, USA, director of operations, Office of the Army Surgeon General, email to MG John Cuddy, 24 Aug 1998, objecting to email from Army Surgeon General LTG Ronald Blanck stating that soldiers should not be <u>forcibly</u> vaccinated. [emphasis is quoted exactly from original]

Counterpoint: "Of the more than 3,000 people who have sought counseling to help decide if they need the extra therapy, more than 700 chose to take additional antibiotics. Four dozen Capitol Hill workers received the first vaccinations on Dec. 20. Since then, an additional 39 people, mostly postal workers, in Washington, New York, New Jersey and Florida have been vaccinated, CDC figures show. U.S. Postal Service officials counted an additional 10 inoculations."

> -- Associated Press, 2 Jan 2002, reporting less than 100 of over 3,000 civilians exposed to anthrax would <u>voluntarily</u> take the BioPort anthrax vaccine

TAB B
Science/Medicine

Issue: AVIP communication to Congress and to the troops has implied that the vaccine is the only way to deal with anthrax and has minimized the known effectiveness of readily available antibiotics to treat it. The post-Sept 11th anthrax attacks have highlighted how little is really known about how to treat inhalation anthrax.

AVIP Point: "Death is the predictable outcome of inhalational anthrax in unvaccinated persons. Once clinical symptoms appear, death is assured, despite the most heroic, state of the art, post-exposure medical intervention and treatment given. Death from anthrax is vaccine preventable."

-- MG G. Robert Claypool, USA, Deputy Assistant Secretary of Defense for Health Operations Policy, et.al., written testimony before the House Government Reform Committee, 21 Jul 1999

Counterpoint: "If the anthrax crisis has taught us anything, it is that neither we — nor the nation's supposed experts in disease and bioterrorism — should trust our instincts or our presumed knowledge. That first became obvious as public health experts struggled to unravel the medical side of this unfolding mystery, only to find that much of what they thought they knew about the disease was probably not true."

--"In Sizing Up Anthrax, Don't Trust Your Gut", New York Times, 7 Dec 2001

Counterpoint: "In defending themselves against growing criticism for not making a firm recommendation, health officials last week were forced to do what they rarely do — confess ignorance about the risks of a disease and its treatment options."

-- "In Offering Anthrax Vaccine, Officials Admit to Unknowns", New York Times, 25 Dec 2001

Counterpoint: "...But that expectation was based on what scientists knew about the 1979 outbreak in Sverdlovsk, which was caused by a plume of spores accidentally released from a bioweapons factory. Now, Dr. Henderson said, scientists realize they misread scientific papers, never appreciating that many more Soviets may have had the disease and survived..."There is a lot of feeling that we didn't know what we were doing as scientists in giving advice," he said. "But, sorry, we haven't had a lot of anthrax around to know just how it's going to behave.""

-- Dr. Donald Henderson, director of the Office of Public Health Preparedness and chief adviser on bioterrorism to HHS Secretary Thompson, quoted in "Anthrax Missteps Offer Guide to Fight Next Bioterror Battle," by Dr. Lawrence K. Altman, M.D., New York Times, 6 Jan 2002

Tab B
Science/Medicine

Issue: DoD has used "expert" committees to assert that there is no connection between anthrax vaccine and Gulf War Illness, but has refused to conduct a study. However, three studies conducted on Canadian, British, and Kansas Gulf War veterans have all found a positive correlation between vaccination against biological warfare threats and Gulf War Illness.

AVIP Point: "...numerous panels of distinguished civilian and military experts have looked at the likelihood of any vaccine, including anthrax, being the cause of the diverse symptoms. These panels have included the Presidential Advisory Commission, the Defense Science Board, the National Institutes of Health and the Institute of Medicine. They all have concluded that there is no evidence of a connection between the illnesses and any of the vaccines, either singly or in combination."

-- LTG Ronald Blanck, Army Surgeon General, Washington Times letter to the editor, 14 March 2000 – referring to "expert" committees that never conducted research.

Counterpoint: "Although anthrax vaccine had been considered approved prior to the Persian Gulf War, it was rarely used. Therefore, its safety, particularly when given to thousands of soldiers in conjunction with other vaccines, is not well established. Anthrax vaccine should continue to be considered as a potential cause for undiagnosed illnesses in Persian Gulf military personnel."

-- then-Major General Ronald Blanck, testimony provided to Senate Veterans Affairs Committee staff, Feb 1994, in Senate Report 103-97

Counterpoint: "There is a paucity of published peer-reviewed literature on the safety of the anthrax vaccine...There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically evaluated with active surveillance...The committee concludes that in the peer-reviewed literature there is inadequate/ insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes."

-- Institute of Medicine (National Academy of Sciences) report to DoD on anthrax vaccine safety, 31 March 2000

Counterpoint: "When it comes to the *long-term* health effects of these substances, the bottom line is we simply don't know enough to say whether there is a connection between exposure to these agents or combinations of agents and specific health outcomes that remain long after the exposure. It will take further research to explore this relationship."

-- Dr. Harold Sox, testimony to Congress on IOM's Gulf War Illness study, 27 Sep 2000

TAB B
Science/Medicine

Issue: AVIP Agency rhetoric to the troops and the media about anthrax vaccine safety has consistently not disclosed DoD knowledge of chronic autoimmune disorders that mirror Gulf War Illness symptoms. However, when CDC was legally required to provide informed consent to postal workers and Congressional staff, they revealed information that has never been given to servicemembers.

AVIP Point: "Lt. Col. John Grabenstein, an army epidemiologist who tracks reactions to the vaccine, says negative side effects are "minimal" given that some 2.1 million doses have been given to 521,000 people since 1998. Some 1,628 of those people have reported problems after getting the vaccine, mainly redness or swelling at the site of the injection. Ten had such massive swelling in their arms after the vaccine that they needed to be hospitalized, a reaction which Dr. Grabenstein acknowledges was probably caused by the vaccine. An additional 15 were successfully treated for anaphylaxis, a potentially fatal allergic reaction, which can cause lungs to spasm and the throat to swell up."

-- "Injecting Doubt: Worries About Safety Of Its Anthrax Vaccine Put the Army in a Bind", Wall Street Journal, 12 Oct 2001

AVIP Point: "If people are getting sick, Colonel Grabenstein said, "it is not due to the vaccine." "

-- "As U.S. Offers Anthrax Shots, Safety Debate Begins Again", New York Times, 20 Dec 2001

Counterpoint: "Risk of a 2nd Epidemic of GWI? High Anxiety & Fear, Low Trust Climate. Potentially more than 25 individuals from same location, having received anthrax vaccinations around the same time & from same lot, growing "belief" that anthrax has caused potentially long term, indefinite, untreatable disease! Fear of military medical establishment: affected service members fail to report."

-- Col (Dr.) Renate Engler, chief of immunology at Walter Reed Army Medical Center, briefing slide for AVIP conference, Ft. Detrick, MD, 25-27 May 1999

Counterpoint: "Some people have reported serious chronic illnesses like Guillian Barre Syndrome (a muscle weakness disease), chronic joint diseases, or had miscarriages and infertility after getting the anthrax vaccine...Although unconfirmed, a recent preliminary study suggests that the vaccine may be linked with an increase in the number of birth defects when given during pregnancy. At this time no one knows for sure whether this vaccine can cause fetal harm."

-- CDC Informed Consent document given to postal workers, Dec 2001

TAB C
Law

Issue: The BioPort/Michigan anthrax vaccine was not licensed in accordance with the law – the Food, Drug and Cosmetic Act -- and remains improperly licensed today because it has never proven efficacious in humans for any route of exposure: cutaneous, ingestion, or inhalation. The FDA has never finalized a 1985 "expert" committee proposal to validate the vaccine license because it lacks the scientific data to do so. Additionally, changes to the vaccine since 1990 were not approved by FDA until 2001, and may have – according to the Army -- increased the potency of the vaccine by a factor of 100.

AVIP Point: "...while there is a paucity of data regarding the effectiveness of Anthrax Vaccine for prevention of inhalation anthrax, the current package insert does not preclude this use...Therefore, I believe your interpretation is not inconsistent with the current label."

> -- Lead Deputy (acting) FDA Commissioner Dr. Friedman letter, March 13, 1997, acquiescing to ASD(HA) Dr. Stephen Joseph's request for an "interpretation"

Counterpoint: "There have been no controlled evaluation studies with the Michigan anthrax product as was done by Dr. Phillip Brachman using the Merck, Sharp and Dohme product."

> -- January 22, 1969, letter from Director, Laboratory Division, National Communicable Disease Center (CDC), to Director, Division of Biologics Standards, NIH.

Counterpoint: "The vaccine manufactured by the Michigan Department of Public Health has not been employed in a controlled field trial..."Anthrax vaccine...efficacy against inhalation anthrax is not well documented...No meaningful assessment of its value against inhalation anthrax is possible due to its extremely low incidence..."

> -- 1985 FDA expert panel product review panel, acknowledging that the Michigan/BioPort vaccine had never met the legal standard for licensure

Counterpoint: "There have been no controlled clinical trials in humans of the efficacy of the currently licensed U.S. vaccine. The vaccine has been extensively tested in animals..."

> -- Col (Dr.) Arthur Friedlander and Dr. Philip S. Brachman, medical text "Vaccines", 1999 edition (p. 635)

Counterpoint: "Published and unpublished data on anthrax vaccine use during the Gulf War and since 1998 show a significantly greater incidence of both local and systemic adverse reactions compared with rates reported in the product insert...these greater levels of adverse reactions could be related to changes in the vaccine associated with the filter changes..."

> -- GAO testimony before House Government Reform Committee, 23 Oct 2001

TAB C
Law

Issue: AVIP violates a law passed in 1998, 10 USC 1107, that requires a Presidential waiver for DoD mandatory use of experimental or investigational drugs. Initial AVIP development in 1995-1996 included meetings and consultation between Army and FDA officials that acknowledged the need for an Investigational New Drug application to license the vaccine for inhalation exposure. This changed in early 1997 within weeks of Secretary of Defense Cohen being confirmed, when the ASD(HA) pressured an acting FDA Commissioner.

AVIP Point: "Anthrax vaccine is approved by the FDA. According to the FDA, DoD is not using anthrax vaccine as an IND..."

-- AVIP website, accessed 5 Jan 2002 (http://www.anthrax.osd.mil)

Counterpoint: "Limited use vaccines and products are defined as those unlicensed experimental vaccines...used in specific contingency situations...Limited use vaccines include...anthrax."

-- Col. (Dr.) Takafuji and Col. (Dr.). Philip K. Russell (former commander of Ft. Detrick), article, Infectious Disease Clinics of North America, March 1990

Counterpoint: "Therefore, the efficacy of the vaccine against biological warfare is unknown. ... The vaccine should therefore be considered investigational when used as a protection against biological warfare."

-- Senate Report 103-97, 8 Dec 1994, Senate Veterans Affairs Committee

Counterpoint: "This vaccine is not licensed for aerosol exposure expected in a biological warfare environment."

-- SAIC Corporation study proposal (written by a retired Army officer) for U.S. Army, 29 Sep 1995 – prepared for Dr. Anna Johnson-Winegar to support formulation of IND application prepared by Army, and submitted by manufacturer on 20 Sep 1996

TAB C
Law

Issue: Since 1999 DoD has pressured FDA to change the Food, Drug and Cosmetic Act to allow biodefense drugs or vaccines to be "fully licensed" without human efficacy data. This change will effectively neutralize 10 USC 1107, which the DoD medical bureaucracy opposed. It will also weaken the 1962 Harris-Kefauver amendments to the Food, Drug and Cosmetic Act, and lower the political accountability for using what are now experimental drugs and vaccines from elected officials to faceless bureaucrats.

AVIP Point: "If the best treatment available to save lives is an IND product, use should not be hindered by non-feasible regulatory compliance requirements."

> -- Acting Asst Sec of Defense for Health Affairs, Rear Admiral (Dr.) Ed Martin, 1997 memo to FDA objecting to an FDA proposal to amend the 1990 "Interim Rule", which later became the basis for 10 USC 1107 (the 1998 "Byrd" amendment).

AVIP Point: "The FDA and DoD are working together to amend the Code of Federal Regulations to allow animal efficacy data to be used in lieu of large-scale human efficacy trials. This mechanism of licensure is vital to provide military service personnel with licensed products."

> -- DoD 2001 Chemical and Biological Defense Program Annual Report to Congress, discussing a Notice of Proposed Rulemaking filed by FDA on 5 Oct 1999

AVIP Point: "Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final rule for the proposal entitled `New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot be Conducted' as published in the Federal Register on October 5, 1999 (64 Fed. Reg.)."

> -- Section 406 of Senate Amendment 2692 to H.R. 3448, passed the Senate, 20 Dec 2001.

Counterpoint: This DoD-sponsored change to the Food, Drug and Cosmetic Act will be used in lieu of <u>any</u> human efficacy trials, not "large-scale" trials.

Counterpoint: The desire by DoD to "provide service members with licensed products" is to preclude the necessity of either granting servicemembers informed consent or for DoD having to obtain a Presidential waiver of informed consent to use what are now experimental or investigational drugs. This is a political, not a medical or ethical, concern.

TAB D
Ethics

Issue: Ethical compromise by senior DoD appointees who placed a political agenda before the welfare of the troops has been the hallmark of AVIP. Their actions were repeated down the civilian and military chains of command. These public statements are directly contravened by DoD and FDA documents.

AVIP Point: "...To date, we have provided more than 1.8 million safe and reliable vaccinations using a vaccine, certified by the Food and Drug Administration, with a 30-year history of safe and effective use, every dose meeting the highest quality and safety standards and backed by additional testing...We put safety first when we started this program two years ago. I'm putting safety first again today..."

> -- Secretary of Defense William Cohen announcement of the curtailment of his anthrax vaccine program because FDA refused to certify BioPort, 10 July 2000

AVIP Point: "There were no issues that FDA had with the purity, the strength, any of the things that they want when that vaccine rolls out at the end, but there were bookkeeping difficulties. They dinged them for that. But there was nothing about what was going on in the anthrax production that made them shut down to do that. It was an upgrade of the plant because of the modernization and increased production requirements."

> -- Senior officer "representing the Army as executive agent" who was unwilling to be named, DoD press briefing, 5 Aug 1999

Counterpoint: "An FDA inspection of MBPI conducted between November 18 and 27, 1996, documented numerous violations ...Although similar deficiencies have been identified during past inspections, MBPI has failed to make satisfactory corrections. FDA has determined that continuing problems represent a failure to comply with the regulations that safeguard the drug and pharmaceutical industry...there have been FDA cited deficiencies which date back to 1988 in that facility, which bring into question matters concerning the production and release of anthrax vaccine prior to, and since, the Gulf War."

> -- Asst Secretary of Defense for Health Affairs Dr. Stephen Joseph, memorandum to OSD/JCS/Services, 14 March 1997

Counterpoint: "The current FDA letter is specific to inspections of MBPI conducted between November 18 and 26, 1996, however, it sites deficiencies dating back to 1993. The nature of these problems raises concerns about the production and release of anthrax vaccine and dictates a review of all anthrax vaccine produced under the current DoD contract and/or used by DoD during and since the Gulf War."

> -- Harold P. Smith, Jr., Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, memorandum to Director, Joint Program Office for Biological Defense, 4 Jun 1997

TAB D
Ethics

Issue: Risk communication, developed by the Army AVIP Agency and fed to the Services, featured ad hominum attacks on servicemembers who have simply asked that AVIP comply with the law, and for DoD to acknowledge and treat servicemembers harmed by the vaccine. These "risk communication" tactics violated guidance in Presidential Review Directive 5.

AVIP Point: "The Department of Defense is committed to fully educating our Service Member population and their families on the purpose and value of anthrax vaccination in an unprecedented manner. We use each of the following communications media to accomplish this goal...A sophisticated anthrax specific website www.anthrax.osd.mil with multiple layers of information and methods for communicating with our Service Member population, their families, and other DOD beneficiaries and concerned members of the American public."

-- Deputy Secretary of Defense Dr. John Hamre, et.al., written testimony before the House Armed Services Committee, 30 Sep 1999

Counterpoint: "Much of the hand-wringing and bizarre allegations about the vaccine is coming from a vocal minority of people who think the "field" is where a farmer works and "Gortex" is one of the Power Rangers. Most of these folks have never spent a single moment in harm's way and have no appreciation of what that sacrifice means and they openly resent the limited budget currently used to finance our nation's defense... ... Unfortunately, those of us who actually have to fight our nation's wars can't afford such childlike optimism about the world we live in. Other groups believe that we are spreading a virus through vaccinations that will weaken our military and allow the uprisal of the New World Order. I don't make this stuff up ladies and gents it's too rich even for Hollywood."

-- Major Guy Strawder (USA), former director, DoD AVIP Agency: "DOD Anthrax Newsletter -- Vol I, Issue #001, 9 Jun 1999 (removed from the DoD AVIP website in Oct 1999 after it was highlighted by Representative Dan Burton in a Congressional hearing.)

Counterpoint: "I am aware that misinformation and rumors abound concerning the anthrax vaccination program. I also believe that much of the incorrect information found on the internet is being disseminated by persons who have their own reasons and agenda for trying to undo this critical force protection program... "

-- former Marine Corps Commandant Gen. Charles C. Krulak, undated (early 1999) statement on AVIP, still on USMC website (accessed 6 Jan 2002)

TAB D
Ethics

Issue: Physicians, including Army medical corps officers associated with AVIP, have contradicted their own previous appraisals of the anthrax vaccine.

AVIP Point: "The anthrax vaccine appears to be safe and offers the best available protection against wild-type anthrax as a biological warfare agent."

> -- Dr. Gerard Burrow, Yale professor of obstetrics and gynecology, hired as "outside expert" to review AVIP prior to implementation, letter to USD(P&R) Rudy DeLeon, 19 Feb 1998

Counterpoint: "The Defense Department was looking for some [sic] to review the program in general and make suggestions, and I accepted out of patriotism. I was very clear that I had no expertise in Anthrax and they were very clear they were looking for a general oversight of the vaccination program."

> -- Dr. Gerard Burrow, letter explaining his refusal to testify as DoD's "outside expert" on AVIP before the House Government Reform Committee, 26 Apr 1999

AVIP Point: Representative Dan Burton and Ft. Detrick expert Col (Dr.) Arthur Friedlander discuss Friedlander's assessment of the anthrax vaccine published in a medical text:

> Mr. Burton. "Oh, I'm sorry, Dr. Friedlander, excuse me. You authored the only peer-reviewed efficacy study on anthrax in the 1999 edition of the medical textbook Vaccines. You wrote that the current anthrax vaccine is unsatisfactory for several reasons, including that there is evidence in rodents that the efficacy of the vaccine may be lower against some strains of anthrax than others. Did you write that?"
>
> Colonel Friedlander. "Those statements were made in reference to an idealized vaccine, a goal that we are all approaching..."
>
> > -- Colonel (Dr.) Arthur Friedlander – testimony to the chairman of the House Government Reform Committee, 11 Oct 2000.

Counterpoint: "The current vaccine against anthrax is unsatisfactory for several reasons. The vaccine is composed of an undefined crude culture...There is also evidence in experimental animals that the vaccine may be less effective against some strains of anthrax. Clearly a vaccine that is completely defined, that is less reactogenic, and that requires one or two doses to produce long-lasting immunity would be highly desirable."

> -- Colonel (Dr.) Arthur Friedlander, US Army anthrax expert, quoted in medical textbook "Vaccines", 1994 (and 1999) edition.

TAB E
Recommendations

Recommendation: Adopt biological defense strategy outlined in the joint USD(P&R) and USD(AT&L) memo to SecDef Rumsfeld, August 10, 2001:

- **"The current Anthrax Vaccine Immunization Program will continue at minimum level (critical personnel and projects only)..."**

- **"USD(AT&L) will implement an acquisition strategy to purchase additional bio-detectors and stockpiles of antibiotics to augment force protection in the absence of an anthrax vaccine..."**

- **"USD(AT&L) and USD(P&R) will continue their interagency efforts to develop a national long-range vaccine that will address the full range of requirements of the DOD, DHHS, and other stake-holders in this plan."**

Issue: AVIP, and Force Health Protection doctrine developed in the 1990's, is fundamentally based on vaccines. This basic premise of doctrine led to a dogmatic resistance to considering alternative, transformational technologies that would from result from the "coherent institutional process" called for in the Chu-Aldridge memo. A coherent process would not have implemented AVIP with a stockpile of adulterated vaccine and a manufacturer that was already shut down – and remains so four years later – because it cannot comply with the law.

AVIP Point: "The Services and combatant commanders...view the vaccine as the centerpiece of our defense against the most likely biological warfare threat."

> -- Chairman of the Joint Chiefs of Staff General Hugh Shelton, memo to Secretary of Defense Rumsfeld, 30 Aug 2001, and leaked to CNN less than a week later.

Counterpoint: "Military leaders [JCS] initially were dubious about the need for the anthrax vaccine, instead favoring work on a multipurpose vaccine that could counter a number of biological warfare agents."

> -- "Military Chiefs Back Anthrax Inoculations", Washington Post, 2 Oct 1996

Counterpoint: "We need to revise our understanding of the biological weapons threat in order to develop an adequate defense. Rather than responding to specific threats, which are variable and can change rapidly by virtue of biotechnology, we should develop measures that are sufficiently broad-spectrum to address potential biological threats before they exist...."

> -- Ken Alibek, M.D., former deputy director of Soviet bioweapons program, now President, Advanced BioSystems, Inc., testimony before House Armed Services Committee, 20 Oct 1999

TAB E
Recommendations

Recommendation: Use BioPort vaccine only under provisions of Title 10 USC 1107 and DODD 6200.2 as advised by both Republican and Democratic critics of AVIP.

- **Acknowledge that the BioPort/Michigan anthrax vaccine has never proven efficacious in humans for any route of administration and that it should not be considered "fully licensed."**

- **Settle the Buck/Bates Declaratory Judgment lawsuit.**

- **The imminent passage of H.R. 3448 will likely allow mandatory use of the BioPort vaccine without a Presidential waiver of informed consent.**

- **Fund a non-governmental study of chronic autoimmune disorders associated with the anthrax vaccine and provide health care for those who have them.**

Issue: In early 1997 there was a conscious decision by senior DoD policymakers to abandon the lawful method for implementing AVIP that commenced in 1995. The Bush Administration should neither assume responsibility for these actions, nor defend them. By acting within the law to correct the consequences of the previous Administration's policy, the Bush Administration will restore the trust of the troops, and insure that future Force Health Protection programs are implemented with greater acceptance.

Counterpoint: "...the adverse safety and efficacy information on the anthrax vaccine may be the latest example of the Pentagon's deny-and-then-begrudgingly-admit policy. Service members have a right to be concerned... AVIP is analogous to 'friendly fire' on American service members...The DOD must stop the friendly fire "shots" and regain service members' trust."

-- "Friendly Fire: The Mandatory Military Anthrax Vaccination Program", Duke Law Journal, April 2001

Counterpoint: "The AVIP should be suspended because it lacks an essential element in a medical program: trust. However well-intentioned, the anthrax vaccine effort is viewed by many with suspicion. It is seen as another chapter in a long, unhappy history of military medical malfeasance in which the healing arts are corrupted to serve a lethal purpose."

-- House Report 106-556, 3 April 2000, House Government Reform Committee

Counterpoint: "The timing is ideal for you to demonstrate again the vision, courage and leadership that have characterized your entire career, and simply stop the problematic and illegal policies that you are inheriting."

-- Connecticut Attorney General Blumenthal, letter to SecDef Rumsfeld, 22 Mar 2001

TAB E
Recommendations

Recommendation: Establish a multi-disciplinary "Red Team" to provide balanced oversight of Force Health Protection programs and advice to DoD civilian leadership.

Issue: The failure of AVIP is the result of systemic cultural problems in military medicine. Ethical standards have been compromised because military medicine is held to a lower standard of accountability and external oversight than operational branches of the military. The Armed Forces Epidemiological Board is not organized to perform this function.

Counterpoint: Operational mishaps are career-ending events for military officers, often with UCMJ convictions and courts-martial in the case of cover-ups. Recent cases include:

- USAF F-15 pilots who shot down two US helicopters in Iraq in 1994
- USMC EA-6 pilot who hit a gondola cable in Italy killing 20 civilians in 1998
- USMC infantry captain who ordered a forced march that killed a Marine in 1999
- USN F-18 squadron commander who bombed friendly forces in Kuwait in 2001
- USN submarine commander colliding with Japanese fishing vessel in 2001
- USMC colonel, lieutenant colonel, and captain for covering up maintenance problems in the V-22 aircraft in 2001

Counterpoint: Accountability for military medical mishaps – and cover-ups -- is rare. It only occurred in the recent court-martial of Army Captain (Dr.) Hamner because the case devolved into an issue of inter-Service conflict, stoked by a former Marine Corps commandant.

> "The Hamner case has garnered wide attention in Washington's military and medical circles because of charges made by Tyra's father, retired Marine Col. William Tyra, that Walter Reed and Army officials attempted to "whitewash" negligence at the Army's premier medical establishment -- the hospital charged with overseeing the health of the president."
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> -- "Walter Reed Doctor Admits Lying", Washington Post, 4 Dec 2001